REMARKS

Summary of the Office Action

Claims 1, 3, 9, 10, 13-15, 18, 22, 25, 28, 29, 36, 37, 39, 45, and 46 are pending in this application. In the Office Action dated August 31, 2010, the Examiner has rejected claims 1, 18, and 37 under 35 U.S.C. § 102(b) as being anticipated by Beck, U.S. Patent Application Publication No. 2002/0035345 ("Beck"). Claims 1, 3, 9, 10, 13-15, 18, 22, 25, 28, 29, 36, 37, 39, 45, and 46 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Burson et al., U.S. Patent No. 6,615,078 ("Burson") in view of Henley, U.S. Patent No. 5,415,629 ("Henley") , or Neubauer et al., U.S. Patent No. 5,255,692 ("Neubauer"), and in further view of Beck.

Applicants respectfully traverse the claim rejections and request consideration and withdrawal in light of the remarks to follow.

Applicants' Reply to the Prior Art Rejections

I. Response to the 35 U.S.C. § 102(b) rejection

Independent claims 1, 18, and 37 relate to an electrode for iontophoretic drug delivery system including, *inter alia*, a platform, a retainer operably connected to the platform, a conductor connected to the platform, and a drug delivery matrix being operably connected to the platform and proximate the conductor. The platform, for example, is a base or substrate to which other elements of the electrode are secured (see applicants' Original Specification, paragraph 22; Fig. 1). The retainer is connected to the platform and includes a malleable characteristic. The malleable characteristic enables the retainer to be shaped into a desired configuration and retained, for example, by use of structural memory material (see applicants' Original Specification, paragraphs 18 and 24). The malleable aspect of the retainer also allows the electrode to be bent, molded, and retained into a specific shape to conform, for example, to a variety of body contours (see applicants' Original Specification, paragraph 18). The applicants' original specification further explains that the malleable characteristic of the retainer "enables it to be shaped into a desired configuration and

retained" (paragraph 24). An exemplary retainer that has a malleable characteristic is shown as element 16 in Figure 1 of applicants' originally filed application and discussed at paragraphs 18-25. Independent claim 29 recites a similar feature.

Beck fails to teach or suggest a retainer having a malleable characteristic. Beck discloses an ocular iontophoresis apparatus that includes, *inter alia*, a housing element **22**, current distribution element **24**, medicament containment element **26**, and barrier element **28** (Beck Figs. 2 and 3; paragraph 48). Beck states that, "Barrier element **28** is preferably composed of materials which will provide sufficient resilience to flexing while being flexible to conform to the surface upon which it makes contact with to thereby form a fluid-tight seal" (paragraph 67). However, Beck does not teach or suggest that the barrier element is malleable or that it can otherwise retain its shape when bent. Moreover, because Beck's barrier element is resilient to flexing, the barrier element is prohibited from being malleable and retaining a shape. Identified materials are "soft silicone gels or other silicon compounds which generally conform to the surface upon which they are placed.... It is preferred that the barrier element 28 be composed of low-durometer silicone elastomer gels" (paragraph 67). Elastomers generally flex when stress is applied (in this case an eyeball), but tend to return to their original configuration when the stress is removed. Furthermore, low-durometer elastomer gels are too soft to be shaped into a desired configuration and retain that configuration. Because of the resiliency and softness of the barrier element **28**, it is neither malleable nor is likely to retain a shape. Beck makes no further mention of any flexible or malleable parts, let alone using such a material or component as a retainer. Accordingly, applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. § 102(b) rejection of claims 1, 18, and 37.

II. Response to the 35 U.S.C. § 103(a) rejection

Independent claims 1, 18, 29, and 37 disclose an electrode for iontophoretic drug delivery system including, *inter alia*, a platform, a retainer operably connected to the platform, a conductor connected to the platform, and a drug delivery matrix being operably connected to the platform and proximate the conductor, as discussed above with regard to the 102(b) rejection. Independent claim 29 further discloses a method of using an electrode that involves selecting an electrical

characteristic for a dose control, placing the electrode onto a bodily area, aligning the drug delivery matrix, and conforming a malleable retainer to the bodily area. Burson, whether taken alone or in combination with Henley, Neubauer, and Beck, fails to disclose this subject matter.

In particular, Burson, Henley, Neubauer, and Beck fail to describe, teach, or suggest an iontophoresis electrode with a retainer with a malleable characteristic. The applicants' original specification defines that the malleable characteristic of the retainer "enables it to be shaped into a desired configuration and retained" (paragraph 24). The Office Action contends that:

> [A] person of ordinary skill in the art, modifying the apparatus disclosed by Benson with a drug infusion matrix, as taught be Henley, and moreover, with a structure having shape memory and malleable characteristics, as taught by Neubauer or Beck, would have been considered obvious in the art in view of the proven conventionality of these enhancements, and moreover, because an infusion matrix would have resulted in a more efficient means of drug distribution and shape memory and malleability would have facilitated the deployment of the apparatus on the body. (Office Action, page 4-5)

As discussed above with regard to the 102(b) rejection, Beck fails to describe, teach, or suggest a retainer having a malleable characteristic. Henley was cited by the Office Action as teaching a drug delivery matrix. Henley does not teach or suggest a retainer having a malleable characteristic.

Burson was cited by the action as teaching a platform, a retainer, a conductor operably connected to the platform, a dose controller, and a drug delivery means. While Burson discloses a "gel retaining layer" **126**, Burson does not teach or suggest that this "gel retaining layer" or any other layer includes a malleable characteristic that allows it to retain a desired shape. Instead, Burson teaches that the "gel retaining layer" merely acts to "retain" the two hydrogel inserts **122** and **124** (see Burson, col. 18, lines 34-37). Thus, Burson fails to teach or suggest a retainer having a malleable characteristic.

Neubauer discloses an electrode for implantation in a patient for use in heart defibrillation. The electrode is a sheet **20** formed from metal and used for implanting between a patient's ribs and heart (Neubauer, abstract; col. 3 lines 43-45). While the Neubauer electrode could be made of shape-memory metal to facilitate implantation/forming/fixation of the electrode by the surgeon

(Neubauer, col. 5, lines 46-50), the device does not include any sort of retainer. Thus, Neubauer fails to teach or suggest a retainer having a malleable characteristic. The apparatus created by substituting the electrode Neubauer for the electrodes of Burson would therefore fail to have a malleable retainer element.

Furthermore, the apparatus disclosed by Burson is not compatible with the shape-memory metal taught by Neubauer. Burson discloses an autosensor for use in an reverse iontophoresis system (Burson, col. 18. lines 25-27; Fig. 1). The autosensor includes a patient liner **130**, a collection reservoir assembly **120** comprising two hydrogel inserts, biosensor electrode assemblies **104** and **106**, and support tray **118** (Burson, col. 18, lines 27-39). When using the apparatus of Burson for reverse iontophoresis, current travels from one electrode assembly, through one hydrogel insert, through the patient, through the second hydrogel insert, and to the second electrode Burson, col. 20 lines 8-18).

Adding the shape memory metal as taught by Neubauer to the apparatus disclosed by Burson to create an electrode apparatus with a malleable retainer would require extensive redesign to both the metal electrode of Neubauer and the apparatus of Burson. Inserting the shape-memory metal electrode of Neubauer into the assembly of Burson to act as a retainer would disrupt the current pathway described above. Inserting a shape-memory metal sheet anywhere in the reverse iontophoresis assembly would electrically connect at least the first electrode to the second electrode or the first hydrogel insert to the second hydrogel insert, which would short circuit the device. The current flow extracts substances through the skin through the process of reverse iontophoresis or osmosis (Burson col. 20 lines 13-16); short circuiting the device would render the reverse iontophoresis device nonfunctional. Thus, the shape memory metal as taught by Neubauer cannot be combined with the reverse iontophoresis apparatus of Burson while allowing Burson to retain its intended functionality. The *2010 KSR Guidelines Update* (75 Federal Register 169, 53644-53645) discuss the case of *DePuy Spine, Inc. v. Medtronic Sofamor Danek*, Inc., 537 F.3d 1314 (Fed. Cir. 2009), and clearly establish that "predictability as discussed in KSR encompasses the expectation that prior art elements are capable of being combined, as well as the expectation that the combination would have worked for its intended purpose." Id. at 53649. The addition of the shape-

memory metal electrode of Neubauer to the apparatus of Burson would make reverse iontophoresis impossible, requiring the shape-memory metal electrode to be redesigned, at least in shape or material, to allow the apparatus of Burson to function as a reverse iontophoresis device.

Furthermore, even if the shape-memory metal of Neubauer could be combined with the reverse iontophoresis apparatus of Burson, Burson would need to be extensively redesigned to be malleable and able to retain a shape. Burson teaches that the support tray **118** "typically refers to a rigid, substantially planar platform and is used to support and/or align the electrode assembly and the collection assembly" (Burson, col. 9, lines 37-42). Burson relies on a rigid support tray **118** to support and align the electrode assembly and the collection assembly. To make the apparatus of Burson malleable, one must remove or redesign this support tray. If the support tray is eliminated or made malleable, the iontophoretic electrodes, the biosensor electrodes, and the collection assembly with hydrogel inserts, gel retainer, and mask layer must be redesigned in such a way that they are supported and maintain alignment without the use of a rigid support tray. In particular, the hydrogel inserts in the collection assembly must be properly aligned with the electrode assembly. Fig. 1 of Burson, cited in the Office Action, shows no connection between the collection assembly and the electrode assembly. Rather, the collection assembly is simply layered above the electrode assembly, which is layered above the support tray. Without the support tray holding the collection assembly and electrode assembly rigidly in place, bending or sliding the apparatus may shift the collection and electrode layers relative to each other, disrupting proper contact between the layers.

In order make the apparatus of Burson malleable, one must first design a malleable retainer that does not interfere with the current pathways or safety of the electrode. Second, one must redesign or remove the rigid support tray **118** so that the apparatus can be malleable. Third, one must redesign the elements layered above the support tray such that the electrodes and hydrogel maintain alignment when the apparatus is bent. Thus, the electrode of Neubauer is not compatible with the electrode assembly of Burson. Furthermore, as a federal court has explained a combination of references is not obvious where, "[the] suggested combination…would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate." *In re*

Ratti, 270 F.2d at 813 (CCPA 1959). MPEP 2143.01 VI. To modify Burson would require a major change from the basic principle that Burson's support tray is rigid to support and align the apparatus, as well as significant redesign of the other components of the electrode apparatus so that they are supported and aligned in the absence of a rigid support tray. Because it would require substantial reconstruction, one of skill in the art would not find it obvious to go down that road.

Therefore, Burson, Henley, Neubauer, and Beck, whether taken alone and in combination, fail to describe, teach, or suggest each and every element of Applicants' independent claims 1, 18, 29, and 37, or of claims 3, 9, 10, 13-15, 22, 25, 28, 36, 39, 45, and 46, which are dependent in claims 1, 18, 29, and 37. Accordingly, Applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. § 103(a) rejection of claims 1, 3, 9, 10, 13-15, 18, 22, 25, 28, 29, 36, 37, 39, 45, and 46.

CONCLUSION

Applicants assert that claims 1, 3, 9, 10, 13-15, 18, 22, 25, 28, 29, 36, 37, 39, 45, and 46 are allowable, for at least the reasons set forth above in addition to other distinctive features recited therein, and respectively request that the Examiner withdraw the rejections.

In view of the above, Applicants believe the pending application is in condition for allowance.

Applicants believe no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 18-1945 from which the undersigned is authorized to draw.

Dated: February 25, 2011

Respectfully submitted,

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